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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/601,912   | 06/23/2003  | Richard L. Antrim    | 006401.00399        | 7581             |
| 22908 7590 01/30/2009<br>BANNER & WITCOFF, LTD.<br>TEN SOUTH WACKER DRIVE<br>SUITE 3000<br>CHICAGO, IL 60606 |             |                      |                     |                  |
| EXAMINER   |             |                      |                     |                  |
| BLAND, LAYLA D   |             |                      |                     |                  |
| ART UNIT   |             | PAPER NUMBER         |                     |                  |
| 1623   |             |                      |                     |                  |
| MAIL DATE  |             | DELIVERY MODE        |                     |                  |
| 01/30/2009   |             | PAPER                |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/601,912

**Applicant(s)**

ANTRIM ET AL.

**Examiner**

LAYLA BLAND

**Art Unit**

1623

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 and 34-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 34-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

### **DETAILED ACTION**

This office action is a response to Applicant's amendment submitted November 14, 2008, wherein claims 1, 4, and 36 are amended and claims 3, 5-33, and 37-38 are canceled, and wherein Exhibits A-C are submitted. Claims 1, 2, 4, 34-36, 39, and 40 are pending and are examined on the merits herein.

In view of the cancellation of claims 3, 5-33, and 37-38, all rejections made with respect to those claims in the previous office action are withdrawn.

In view of Applicant's amendment submitted November 14, 2008, the rejection of claims 36-40 under 35 USC 112, second paragraph, for being indefinite with regard to "digestibility" is withdrawn because the term is no longer in the claims.

In view of Applicant's amendment submitted November 14, 2008, the rejection of claims 36-40 under 35 USC 112, first paragraph, for failing to comply with the written description requirement is withdrawn. The claims no longer include the limitation "digestibility of at least..."

In view of Applicant's amendment submitted November 14, 2008, the rejections of claims 26-40 under 35 USC 102(b) as anticipated by or, in the alternative, under 35 USC 103(a) as obvious over Fouache et al. and over Stahl et al. are withdrawn. The claims no longer contain numerical limitations for digestibility.

The provisional rejection of claims 1-10 and 34-40 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 30 and 31 of copending Application No. 11/184,989 is withdrawn because claims 30 and 31 are no longer pending in copending Application No. 11/184,989.

The provisional rejection of claims 1-10, 34, and 35 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 11/292,246 is withdrawn because claims 1-13 are no longer pending in copending Application No. 11/292,246.

### ***Claim Objections***

The claim identifier for claim 36 is "previously presented," but claim 36 is amended.

The following new rejections were necessitated by Applicant's amendment submitted November 14, 2008, wherein the limitations "substantially digestible by mammalian enzymes" and "a majority of the linking bonds are 1,4-bonds" were added to independent claims 1 and 36.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 4, 34-36, 39, and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 36 (and all dependent claims) recite the limitation "substantially digestible by mammalian enzymes." "Substantially digestible" is a relative term which

renders the claim indefinite. The specification states that the products may be "substantially inert" to digestion by mammalian enzymes or alternatively may be "substantially digestible" but digestible slowly relative to glucose. It is unclear which degree of digestibility is substantial, and it is unclear how digestibility is determined.

### ***Response to Arguments***

Applicant argues that the specification discusses a number of products that are essentially indigestible, including Fibersol, as opposed to "substantially digestible," which serves to demarcate the claimed invention from the essentially indigestible products of the prior art. This argument is not persuasive because the specification provides no standard to determine which products are "substantially digestible," other than the claimed products. The term "substantially digestible" not defined in the specification and no standard is given for how to determine if a product is substantially digestible. The only guidance which is given is that the products are not "inert" to digestion by mammalian enzymes, but are digestible slowly relative to glucose. Thus, the skilled artisan would not understand which products are substantially digestible.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 34-36, 39, and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Okhuma et al. (US 5,358,729, October 25, 1994).

Okhuma et al. teach a product which was prepared by extrusion of corn starch in the presence of hydrochloric acid [column 14, Experimental Example 1]. Characteristics of the products prepared are shown in Table 4. Sample No. 1, for example, contains 53.6% of 1,4-bonds and also contains 1,3- and 1,2-bonds. Sample No. 1 contains 53.3% of indigestible component. Thus, the remaining 46.7% of Sample No. 1 is digestible, which is considered substantially digestible. A different product had 62.3% of 1,4-bonds, as well as 1,2- and 1,3-bonds, and contained 44.2% of indigestible component [Table 7, first entry]. Limitations regarding how the extrusion reaction is performed, such as internal sample temperature, do not add patentable weight to the claims. Thus, the claims are anticipated.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4, 34-36, 39, and 40 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Stahl et al. (WO 01/33973, May 17, 2001, human translation).

Stahl et al. teach a modified carbohydrate made of a base body and a carbohydrate residue coupled therewith [abstract]. In example 1, maltodextrin was derivatized with glucose residues [pages 19-21 of human translation document]. Products obtained by derivatization of maltodextrin with glucose in the 1-2, 1-3, 1-4, or 1-6 position are specifically claimed [claim 4], and are preferably obtained by the use of transglucosidase from *Leuconostoc mesenteroides* [claim 5]. Pancreatine digestion of the product of Example 1A is shown and is lower than maltodextrin [page 31].

Stahl et al. do not teach the percentage of bonds which are 1,2-, 1,3-, 1,4-, or 1,6-bonds. However, since Stahl's product is a derivatized maltodextrin, which has 1,4-bonds, and because Stahl et al. teaches that the product of Example 1A is digestible [claim 1 and Figure on page 31], the skilled artisan would expect that Stahl's product contains a majority of 1,4-bonds. Further, Stahl provides guidance for the desirable characteristics of the product, glucose release [claim 1], and provides guidance for the use of other enzymes [page 17 and 18], and for variation of process conditions [page 19-25]. Thus, the skilled artisan would have motivation and guidance to optimize process conditions to obtain a product with moderated glucose release. "Substantially digestible" is vague and indefinite, as discussed above. Based on the guidance provided on page 11 of the instant specification, as discussed above, a product which is not inert to mammalian enzymes and which is digested more slowly than glucose is considered substantially digestible.

***Response to Arguments***

Applicant argues that, because the claimed product is prepared in an extruder, it differs from Stahl's product because it will include beta bonds and will include a more random assortment of bonds. Applicant also presents Exhibit C to show that *Leuconostoc mesenteroides* NRRL B-512F creates mostly 1,6-bonds. This argument is not persuasive because the claims do not require the presence of beta bonds and it is not clear whether "extrusion" will necessarily result in a product having those bonds. The specification, page 11, states that "it is believed that relatively low levels of chemical modification of the starting material will produce a product having some non 1-4 linking bonds, (e.g. 1-2, 1-3, or 1-6 bonds)." It is noted that Stahl teaches a product having these bonds. The specification, page 10, also states that the extruder can be any conveying device in which temperature, vacuum, water, and starting materials can be introduced with adequate mixing to result in derivatization, and that barrel temperatures can be as low as 25°C. Because the recited process conditions are so broad, and because it is unclear from the specification which particular conditions are required to produce beta bonds, Applicant's argument is not persuasive.

Applicant argues that Stahl's product is specific and well-defined, unlike the claimed product which has randomly produced bonds of several types. This argument is not persuasive because the claims require a product which has a majority of 1,4-bonds, is "substantially digestible," and may also contain 1,2- and 1,3-bonds. Stahl's product meets those limitations, as discussed above.

The following rejections are record are maintained:



***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4, 34-36, 39, and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Meyers et al. (US Patent 5,518,739).

Meyers et al. teach Fibersol, a maltodextrin derivatized with dextrin via glycosidic linkages such as  $\alpha$ -1,6,  $\beta$ -1,2,  $\beta$ -1,3 and  $\beta$ -1,6 (col.3, lines 22-24). As recognized by Applicant in the declaration of Dr. Mungara submitted August 7, 2007 and in the response submitted November 14, 2008, Fibersol has 51.5% of 1,4-bonds and is digested by mammalian enzymes more slowly than glucose. As mentioned above, “substantially digestible by mammalian enzymes” is vague and indefinite. Because Fibersol is not inert to mammalian enzymes, as shown in the declaration of Dr. Mungara submitted November 14, 2008, and is digested slowly relative to glucose, it is considered “substantially digestible.” Limitations regarding how the extrusion reaction is performed, such as internal sample temperature, do not add patentable weight to the claims. Thus, the claims are anticipated.

***Response to Arguments***

Applicant argues that Fibersol is not substantially digestible and presents Exhibits A and B which state that Fibersol is 89% fiber. As mentioned above, "substantially digestible" is vague and indefinite. Based on the guidance provided on page 11 of the instant specification, as discussed above, a product which is not inert to mammalian enzymes and which is digested more slowly than glucose is considered substantially digestible. Exhibits A and B show that a portion of Fibersol is digestible, which was also shown in the declaration of Dr. Mungara submitted November 14, 2008 and Fibersol is thus considered "substantially digestible." Thus, the rejection is maintained.

Claims 1, 2, 4, 34, and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoshida et al. (US Patent 4,840,807).

Yoshida et al. disclose maltodextrin derivatized with dextrin via glycosidic linkages such as  $\alpha$ -1,6 and  $\alpha$ -1,4 (claim 1). The saccharide composition of the product consisted of 2% glucose, 5% maltose, 15% maltotriose, 6% maltotetraose, 12% maltopentaose, 20% maltohexaose, and 50% of branched dextrin column 6, Example 1]. Thus, at least 58% of the product was composed of maltooligosaccharides, which are 1,4-linked. Yoshida does not disclose the digestibility of the product. However, because Yoshida's product has primarily 1,6-linkages and 1,4-linkages [claim 1], it would be expected to be digestible. Since the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the

burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). Limitations regarding how the extrusion reaction is performed, such as internal sample temperature, do not add patentable weight to the claims.

### ***Response to Arguments***

Applicant argues that Yoshida's product has only 1,4- and 1,6-bonds and that a product prepared in an extruder would have other bonds including 1,2-, 1,3- and beta bonds. This argument is not persuasive because the claims do not require the presence of those other bonds and it is not clear whether "extrusion" will necessarily result in a product having those bonds. The specification, page 11, states that "it is believed that relatively low levels of chemical modification of the starting material will produce a product having some non 1-4 linking bonds, (e.g. 1-2, 1-3, or 1-6 bonds)." The specification, page 10, also states that the extruder can be any conveying device in which temperature, vacuum, water, and starting materials can be introduced with adequate mixing to result in derivatization, and that barrel temperatures can be as low as 25°C. Because the process conditions are so broad, and because it is unclear from the specification which particular conditions are required to produce non 1-4 linking bonds, Applicant's argument is not persuasive and the rejection is maintained.

Claims 1, 2, 4, 34-36, 39, and 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Fouache et al. (US Patent 6,630,586).

Fouache et al. disclose maltodextrin derivatized with dextrin via glycosidic linkages such as  $\alpha$ -1,6 and  $\alpha$ -1,4 (claim 1). Fouache et al also disclose maltodextrin derivatized with dextrin via glycosidic linkages such as 1-2, 1-3, 1-4, and 1-6 (Co1.8, Tables I and II). Products having 50% or 95% of 1,4-linkages are exemplified [column 8, Table I]. The product having 50% of 1,4-linkages also had 10% each of 1,2- and 1,3-linkages. As discussed above, it is not clear whether "extrusion" will necessarily result in a product having 1,2- and 1,3-bonds and thus claims 1, 2, 4, 34, and 35 are anticipated by products D and E of Table I, which have 95% 1,4-bonds. Product C is disclosed by Fouche et al. as having 50% 1,4-linkages. Applicant's response submitted November 14, 2008 indicates that the percentage of 1,4-bonds in the Nutriose product was experimentally determined to be 49.6% by Dr. Mungara, when multiple linkages are counted. Using the declaration of Dr. Mungara submitted August 7, 2007 (Table 2), the examiner added the percentages for all the 4-glc values for Nutriose, including the multiple linkages. 4-glc was indicated on page 4 of the declaration to be where a branch point existed at the 4-position. The result of that calculation was 55.7%, which is a majority. The declaration of Dr. Mungara submitted August 7, 2007, also indicated that Nutriose was digested by mammalian enzymes, as was similarly discussed above for the Meyers reference. Thus, the claims are anticipated.

### ***Response to Arguments***

Applicant argues that the digestibility of Nutriose is only about 15%. This argument is not persuasive because "substantially digestible" is vague and indefinite, as discussed above, and because any product which is not inert to mammalian enzymes

but is digested more slowly than glucose is considered "substantially digestible," also discussed above.

Applicant argues that Nutriose does not contain a majority of 1,4-bonds. The declaration of Dr. Mungara submitted August 7, 2007, appears to contradict this argument as discussed above. Thus, the rejection is maintained.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 34-36, 39, and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Stahl et al. (WO 01/33973, May 17, 2001, human translation).

Stahl et al. teach a modified carbohydrate made of a base body and a carbohydrate residue coupled therewith [abstract]. In example A1, maltodextrin was derivatized with glucose (dextrose monohydrate) residues [page 13, lines 8-21 of original document and page 4 of machine translation, Example 1, Variant A]. The digestible base body or carbohydrate can preferably be dextrin [page 6, lines 7-9 of original document and page 2 of machine translation, second paragraph from the bottom]. The DP of the base carbohydrate is preferably 3-100 but can be up to 100,000 [page 5, lines 12-15 of original document or page 2, paragraph 10 of the machine

translation]. Products obtained by derivatization of maltodextrin with glucose in the 1-2, 1-3, 1-4, or 1-6 position are specifically claimed [claim 4].

Regarding claims 1 and 35, the patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698,227 USPQ 964, 966 (Fed. Cir. 1985).

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAYLA BLAND whose telephone number is (571)272-9572. The examiner can normally be reached on Monday - Friday, 7:00 - 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shaojia Anna Jiang/  
Supervisory Patent Examiner, Art Unit 1623

/Layla Bland/  
Examiner, Art Unit 1623